MHIRB Administration
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Methodist Healthcare

May 1, 2002

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Food and Drug Administration
Document Management Branch
5630 Fishers Lane RM 1061
Rockville, MD 20852

RE: Docket No. 01N-0322 IRB: Requiring Sponsors and Investigators to Inform IRBs of any Prior IRB Reviews

To Whom It May Concern:

Please accept the following comments in response to the proposed rule change that would require investigators to inform IRBs of prior IRB review.

1. IRB shopping: Because of the private status of our institution the investigator has no option for IRB shopping when desiring to conduct research at Methodist Healthcare (MH). However, a few (<5) investigators over the past 3 years have decided to not conduct their research here because they must go through the MHIRB. Obviously they were then candidates for IRB shopping.
2. Who should make the disclosure: The sponsor should disclose all IRB decisions to the investigator, who should in turn present this information at the time the study is submitted to the IRB for initial review. It should be incumbent upon the investigator to present the information to the IRB, just as it is to present other pertinent information at the time of initial submission. The sponsor should notify all investigators of decisions from the various IRBs where the study has been reviewed.
3. Who should receive the disclosure: The IRB that is reviewing the study should receive all known information about other IRB decisions. Just as safety information is forwarded from the sponsor to the investigator, who forwards it to the IRB, information on IRB decisions should follow this same venue. An IRB should receive information about all IRB decisions, even after the IRB has ruled. We have on rare occasion received information about revisions to an active protocol in this manner, whereby the investigator received information from the sponsor and the investigator then sent the information to the IRB of record. Upon receipt of the information about the other IRB ruling we then reexamined the revision and required further documentation from the investigator. We subsequently did not alter our original decision, but were making an informed decision.
4. What information should be disclosed: Information about the decision and any requirements that change the risk to the subject should be sent to other IRBs considering the study. The information can be in summary form to avoid undue paper work with the proviso that more, detailed information is available upon request.

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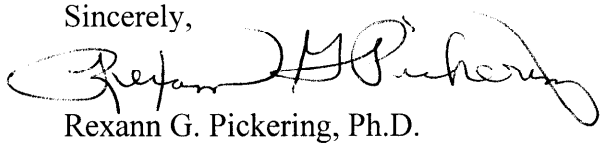
5. If a proposal would not require disclosure of all prior IRB decisions, what information should be disclosed: All information that alters the risk determination should be disclosed. This may entail, unfavorable reviews, but also decisions about the relative risks. However, all prior reviews should be disclosed, again, the data can be in summary format.
6. To permit a subsequent IRB to assess the value of a prior IRB decision, should information about the basis for the prior decision be disclosed: Information can be disclosed as to the decision and allow the reviewing IRB to determine whether more information is needed. If so, the reviewing IRB can contact the IRB that rendered the decision in question for more information. I have done this on several occasions and found the other IRBs to be helpful.
7. How should FDA enforce the requirement: Consider the process for disclosing other information such as adverse event and follow suit. Also, documentation can be required when an investigator submits a 1572 that documents this. If it is important enough to be considered a part of the federal regulations, then it should b enforced as other like parts.

Thank you for your consideration of these comments and for offering the opportunity to respond.

Sincerely,



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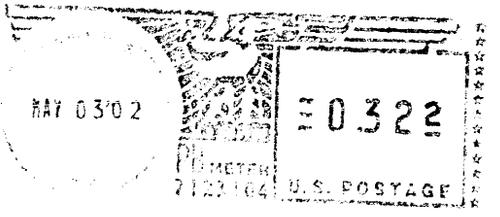

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